UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NOVARTIS AND PAR ANTITRUST LITIGATION	Case No. 1:18-cv-04361-AKH
RITE AID CORPORATION & RITE AID HDQTRS. CORP. AND CVS PHARMACY, INC., Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, & PAR PHARMACEUTICAL, INC., Defendants.	Case No. 1:18-cv-11835-AKH JURY TRIAL DEMANDED

AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs CVS Pharmacy, Inc., Rite Aid Corporation and Rite Aid Hdqtrs. Corp. ("Plaintiffs") bring this civil action against Defendants Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis") and Par Pharmaceutical, Inc. ("Par") (Novartis and Par are collectively "Defendants"). For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking permanent injunctive relief, treble damages and other relief arising out of Defendants' unlawful exclusion of generic competition to the brand-name drug Exforge, an FDA-approved prescription drug used to treat hypertension, the active ingredients of which are amlodipine and valsartan. Defendants entered into an unlawful

agreement under which Par agreed not to compete with Novartis by launching a generic version of Exforge and, in return, Novartis agreed not to compete with Par by launching an authorized generic version of Exforge during Par's exclusivity period. Such an agreement is both a per se unlawful horizontal market-allocation agreement and an unlawful reverse-payment agreement that had substantial anticompetitive effects in the relevant market.

2. Prior to the market entry of generic Exforge, Novartis's annual U.S. sales of branded Exforge exceeded $400 million.

3. Generic manufacturers Par and Synthon Pharmaceuticals Inc. ("Synthon") recognized the market potential for generic Exforge and were the first generic manufacturers to seek FDA approval to market a generic version of Exforge. Par and Synthon filed Abbreviated New Drug Applications ("ANDAs") with the FDA in October and November 2007.

4. Par was the first ANDA filer for the 10/160, 5/160 and 10/320 milligram strengths of Exforge, while Synthon was the first ANDA filer for the 5/320 milligram strength. Upon filing their ANDAs, Par and Synthon provided the required certifications (as explained below) to three patents that Novartis had listed in the FDA's "Orange Book": U.S. Patent No. 5,399,578 (the '578 Patent); U.S. Patent No. 6,294,197 (the '197 Patent); and U.S. Patent No. 6,395,728 (the '728 Patent). Par and Synthon filed paragraph III certifications to the '578 Patent, agreeing that they would not seek to market their proposed generic products prior to the September 21, 2012, expiration of that patent. Par and Synthon filed paragraph IV certifications to the '197 and '728 Patents, indicating that they were seeking approval to market their proposed generic products prior to the expiration of those patents because those patents were either invalid or would not be infringed by Par's and Synthon's proposed products, or both.

5. On November 30, 2011, Par entered into an agreement with Synthon to purchase Synthon's ANDA for generic Exforge. That agreement closed on December 30, 2011.

6. Novartis did not sue Par or Synthon for patent infringement based on their paragraph IV certifications to the '197 and '728 Patents. Instead, sometime in 2011, Par and Novartis reached an agreement whereby (1) Par agreed not to launch a generic version of Exforge until September 30, 2014, thereby allocating the entire Exforge market to Novartis until more than two years after the expiration of the '578 Patent; and (2) Novartis agreed not to compete with Par by launching an authorized generic ("AG") version of Exforge during Par's 180 days of exclusivity, thereby allocating all generic sales during that period to Par.

7. On March 9, 2010, the FDA granted tentative approval to Par's ANDA for generic versions of Exforge. Par's approval was tentative rather than final because of its paragraph III certification to the '578 Patent.

8. On March 28, 2013, the FDA granted final approval to Par's ANDA for generic versions of Exforge.

9. Because of the unlawful agreement between Novartis and Par, Par did not launch its generic version of Exforge upon receiving final approval in March 2013 and instead delayed its launch until September 30, 2014. Pursuant to the same agreement, Novartis delayed the launch of its AG until March 30, 2015. Absent the agreement, Par would have launched a generic version of Exforge as early as September 21, 2012, when the '578 Patent expired, and in any case no later than March 28, 2013, the date of final FDA approval, and Novartis would have launched an authorized generic simultaneously, thereby lowering the price of both Par's generic and Novartis's authorized generic. Thus, the unlawful agreement deprived Plaintiffs and other

purchasers of the ability to purchase less expensive generic Exforge from as early as September 21, 2012 to September 30, 2014, and also deprived Plaintiffs and other purchasers of the ability to purchase less expensive generic Exforge from September 30, 2014 to March 30, 2015.

10. By entering into and carrying out their unlawful agreement, Defendants violated sections 1 and 2 of the Sherman Act. Their conduct unlawfully maintained and prolonged Novartis's monopoly power in the relevant market; foreclosed and delayed competition from lower-priced generic versions of Exforge; foreclosed and delayed competition from an authorized generic version of Exforge; and fixed, raised, maintained, and stabilized the price of Exforge and its generic equivalents at supracompetitive levels.

11. As a result of Defendants' antitrust violations, Plaintiffs and/or their assignors suffered injury in the form of overcharges for both branded and generic Exforge. Plaintiffs bring this action to recover those overcharges, as well as other relief.

II. PARTIES

12. Plaintiff CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Pharmacy, Inc. purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 9,600 drugstores, approximately eleven mail service pharmacies, and twenty-seven specialty pharmacies owned and operated by its affiliates. Plaintiff CVS Pharmacy, Inc. brings this action on its own behalf and as the assignee of McKesson Corporation and Cardinal Health, Inc., which during the relevant period each purchased Exforge directly from

Defendants for resale to CVS Pharmacy, Inc., and which has assigned its claims arising out of those purchases to CVS Pharmacy, Inc.

13. Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (collectively "Rite Aid") are corporations organized and existing under the laws of the State of Delaware with a principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public. Rite Aid brings this action on its own behalf and as the assignee of McKesson Corporation, which during the relevant period purchased Exforge directly from Defendants for resale to Rite Aid and which has assigned its claims arising out of those purchases to Rite Aid.

14. Defendant Novartis Pharmaceuticals Corporation is a Delaware corporation having its principal place of business at One Health Plaza, East Hanover, New Jersey 07936. Novartis Pharmaceuticals Corporation is a subsidiary of Defendant Novartis AG and the entity that manufactures, markets, and sells Exforge in the United States.

15. Defendant Novartis AG is a Swiss corporation having its principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland. It is the parent of both Novartis Corporation and Novartis Pharmaceuticals Corporation.

16. Defendant Par Pharmaceutical, Inc. is a Delaware corporation having its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977. Its principal business is developing, manufacturing and marketing generic drugs in the U.S.

17. All of Defendants' actions described in this Complaint were carried out by Defendants' various officers, agents, employees, or other representatives while actively engaged

in the management of Defendants' affairs and within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

18. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover permanent injunctive relief, treble damages, costs of suit and reasonable attorneys' fees for the actual and threatened injuries sustained by Plaintiffs resulting from Defendants' unlawful foreclosure of the United States market for Exforge and its AB-rated generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

19. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §1391(b) and (c).

IV. BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

20. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's

choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

21. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Exforge, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

22. Defendant Novartis and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a less significant role in product selection than in other industries.

23. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is

what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

24. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

25. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

26. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

27. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 STAT. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

28. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

29. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

30. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had increased many-fold to $300 billion.

D. Paragraph IV Certifications

31. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
ii. that the patent for the brand drug has expired (a "Paragraph II certification");
iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

32. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not

infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot grant final approval or authorize the generic manufacturer to market its product. The FDA may grant tentative approval to a generic applicant when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

33. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other ANDA applicants (although not from an "authorized generic," as discussed below). For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of exclusivity. This means that the FDA will not approve subsequently filed ANDAs for 180 days. This 180-day exclusivity period is valuable to generic companies. With only one generic on the market, the generic price is typically 25-30% below the price of the branded drug, but this discount increases to 50% or more when more than one generic competitor is on the market, and can go as high as 90% with multiple generic competitors. Being able to sell without competition from other ANDA filers for six months may be worth hundreds of millions of dollars.

34. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of other generic manufacturers. The first ANDA filer, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity. This creates a "bottleneck" because later filers cannot launch until the first filer's 180-day exclusivity has elapsed or is forfeited.

E. Benefits of Generic Drugs

35. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as Plaintiffs, a generic typically achieves at least an 80% substitution rate within 90 days. As a result, brand name companies, such as Novartis, view competition from generic drugs as a grave threat to their bottom lines.

36. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments in 1984, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

37. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices of generic products.

38. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the agreement at issue here.

F. The Impact of Authorized Generics

39. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period pursuant to its own approved NDA. Such an "authorized generic" is literally identical to the brand drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both the ANDA filer's generic drug and the authorized generic and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

40. In its study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) ("Authorized Generic Drugs"), the Federal Trade Commission found that authorized generics capture a significant portion of sales and reduce the revenues generated by the first-filer's generic product by approximately 50% during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an

authorized generic because (1) the authorized generic takes a share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes generic prices to decrease.

41. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

42. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same rate that they raised it prior to generic entry.

43. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers often use such agreements as a way of compensating the first-filer for delaying its entry into the market. Such agreements deprive Plaintiffs and other purchasers of the drug of the lower prices resulting from two forms of competition. During the initial period of delay agreed to by the ANDA filer, they effectively eliminate all competition from AB-rated generic products and allow the brand manufacturer to preserve its monopoly. And, during the period in which the branded company

has agreed not to sell an authorized generic, they eliminate competition between the ANDA filer's generic and the brand manufacturer's authorized generic, giving the ANDA filer a monopoly on all generic sales.

44. As a means of compensating first-filing generic manufacturers, brand manufacturers prefer no-AG agreements to cash payments because, in the case of no-AG agreements, a portion of the compensation is paid by purchasers of the drug in the form of higher generic drug prices. The generic manufacturer receives not only the profits that the brand manufacturer would have made by launching an authorized generic in competition with the ANDA filer's product, but also the higher prices that result from the absence of that competition. Thus, the payment to the generic manufacturer is shared between the brand manufacturer and the generic manufacturer's customers.

V. OPERATIVE FACTS

A. Defendants' Products and the Nature of Sales of Generic Equivalent Products

45. In the United States, high blood pressure (HBP or hypertension) affects an estimated one of three adults or about 75 million people. According to the American Heart Association, if left untreated, high blood pressure can lead to, among other serious health complications: heart attack, stroke, heart failure, kidney disease and peripheral artery disease. High blood pressure was a primary or contributing cause of death for more than 410,000 Americans in 2014—more than 1,100 deaths each day.

46. As of 2007, the most commonly prescribed branded high blood pressure medicines in their respective classes were the calcium channel blocker ("CCB") amlodipine

(marketed as the besylate salt under the brand name Norvasc) and the angiotensin-II receptor blocker ("ARB") valsartan (marketed under the brand name Diovan).

47. Novartis already had intellectual property rights to Diovan, but its plan was to combine the active ingredients in Diovan and Norvasc, the latter of which is a Pfizer product, as soon as Pfizer's patents expired in September 2007. However, on March 22, 2007, the United States Court of Appeals for the Federal Circuit invalidated Pfizer's Norvasc patents, paving the way for earlier FDA approval of Novartis' Diovan/Norvasc combination (Exforge).

48. On June 20, 2007, the FDA approved Novartis's NDA No. 21-990 for Exforge tablets, the first high blood pressure medication to combine both amlodipine and valstartan in a single medication. Shortly thereafter, Exforge tablets were launched in the U.S. Exforge quickly became one of the most commonly prescribed branded high blood pressure medicines.

49. Novartis claimed that Exforge, the combination of valsartan and amlodipine, offered patients the convenience of a reduced pill load for their hypertension medication, increasing patient adherence.

B. Novartis's Patents

50. Novartis listed three patents in the FDA Orange Book under NDA No. 21-990 for Exforge: the '578 Patent, the '197 Patent, and the '728 Patent. The '578 Patent, which disclosed and claimed the chemical compound valsartan, expired on March 21, 2012. A regulatory exclusivity known as pediatric exclusivity that attached to the '578 Patent expired on September 21, 2012. As Par and Synthon recognized, neither the '197 Patent nor the '728 Patent afforded Novartis the right or ability to exclude generic competition for Exforge, and therefore Novartis

had no legitimate basis for excluding generic competition after September 21, 2012. Had Novartis chosen to litigate the validity or infringement of the '197 and '728 Patents in the courts, those patents would have been adjudged invalid, unenforceable, and/or not infringed.

51. On or about October 1, 2007, Par filed ANDA No. 90-011. Par's ANDA No. 90-011 included paragraph IV certifications for the '197 and '728 Patents. The paragraph IV certifications stated that "each of these [two] patents is invalid, unenforceable, or will not be infringed by [Par's] manufacture, use, or sale of Amlodipine and Valsartan Tablets, 5 mg/160 mg, 10 mg/160 mg, and 10 mg/320 mg" described in ANDA No. 90-011. Par notified Novartis of its paragraph IV certifications and the bases for them, but Novartis never sued Par for patent infringement. Novartis chose not to sue because it recognized that the patent defenses set forth in Par's paragraph IV certification notice letter were meritorious and would have succeeded had they been litigated.

52. No valid claim of the '728 Patent was infringed by Par's filing of ANDA No. 90-011 or the manufacture or sale of Par's generic version of Exforge. First, the claims of the '728 Patent are properly construed to be limited to the use of a combination of valsartan and amlodipine for the treatment of hypertension in the limited subset of patients suffering from diabetes and could not have afforded Novartis any right to exclude generic competition beyond that very narrow use. The '728 Patent issued from United States Application Serial No. 09/757,413 (the "'413 Application"), which is a divisional of United States Application Serial No. 09/349,654 (the "'654 Application"). The original claims of the '654 Application broadly recited (1) "[a] method for the treatment or prevention of [a wide variety of different disease states] comprising administering a therapeutically effective amount of a combination" of

valsartan, a calcium channel blocker and a pharmaceutically acceptable carrier; and (2) "[a] pharmaceutical combination composition comprising" those same ingredients. As originally filed, those claims were not limited to the use of valsartan and amlodipine in the treatment of patients suffering from diabetes. *Id.*

53. However, the examiner at the United States Patent and Trademark Office rejected each of those claims as obvious in view of United States Patent No. 5,492,904 (the "'904 Prior Art Patent") and the prescribing information for Diovan (the "Prior Art Diovan Literature"). The examiner noted that the '904 Prior Art Patent taught the combined use of an angiotensin-II antagonist (like valsartan) and a calcium channel blocker (like amlodipine):

> [The '904 Prior Art Patent] teach[es] pharmaceutical compositions which comprise an angiotensin-II antagonist and a calcium channel blocker of the type presently claimed which are useful in the treatment of hypertension and congestive heart failure. See the abstract and column l, lines 25-40. It is further taught that the compositions may comprise from 10 to 300 mg of the desired calcium channel blocker and from 1 to 100 mg of the angiotensin-II antagonist.

54. The examiner acknowledged that the '904 Prior Art Patent did not teach valsartan, but noted that the Prior Art Diovan Literature "discloses that valsartan was a well-known angiotensin-II antagonist." Accordingly, the examiner deemed the originally-claimed subject matter to be obvious.

55. The applicants for the '654 Application amended their claims, but the examiner reiterated his rejection. In response to the rejection, the applicants amended method of use claim 1 by deleting the broad recitation of disease conditions and narrowing it to the treatment of

"hypertension ***associated with diabetes***." Thereafter, the '654 Application issued as United States Patent No. 6,204,281.

56. The '413 Application was filed as a divisional application on January 9, 2001 along with a preliminary amendment whose claims were similar to those that had been originally filed in the '654 Application. The examiner rejected the claims pending in the '413 Application as obvious for the same reason he had rejected the claims in the '654 Application. In response to the rejection, and consistent with their amendment in the '654 Application, the applicants limited claim 1 to the treatment of "hypertension associated with diabetes." In explaining why the amendment would overcome the examiner's obviousness rejection, which applied to all pending claims including the method claims, the applicants argued that they had shown unexpected results in the treatment of diabetes:

> Applicants have clearly shown unexpected results in the treatment of [diabetes] associated with hypertension with the combination of valsartan and verapamil. For example, on page 6 to page 7 of the instant application (inserted by this amendment), Applicants have shown that treatment with the combination of valsartan and verapamil resulted in a considerable reduction of sudden death events and significant degree of increase of the survival rate as compared to the administration of the single drugs alone. These unexpected results are sufficient to overcome the obviousness rejection based on the references because a combination of the references do not teach or suggest the treatment of hypertension associated with diabetes.

57. Thus, while the composition of matter claims did not refer explicitly to diabetes, the applicants' argument was premised on the view that those claims were limited to the use of the claimed pharmaceutical composition in patients suffering from diabetes. "Claims 1-9 have

been rejected . . . . Applicants respectfully traverse this rejection. ***The claims are now directed to hypertension associated with diabetes.***" (emphasis added).

58. The examiner nevertheless again rejected the claims. In response, the applicants further amended the claims to limit them to the use of valsartan with amlodipine. In doing so, they again made clear that both the method of use and composition of matter claims should be viewed as limited to the use in the "treatment of hypertension associated with diabetes":

> Claims 1, 4 and 9 have been amended to recite amlodipine as the selected calcium channel blocker. The treatment of hypertension associated with diabetes by administering a combination of valsartan and amlodipine is neither taught nor suggest by the cited references. Accordingly, the rejection has been overcome and should be withdrawn.

Par was not seeking FDA approval to market its product for the treatment of hypertension associated with diabetes, and therefore could not induce infringement of any claim that was limited to this use.

59. In addition, the claims of the '728 Patent are invalid in view of the prior art. The '904 Prior Art Patent issued on February 20, 1996, more than three years before the earliest possible effective filing date of the '728 Patent, and is therefore prior art to the '728 Patent. The '904 Prior Art Patent is titled "Composition of Angiotensin-II Receptor Antagonists and Calcium Channel Blockers" and teaches the use of a pharmaceutical composition comprising an angiotensin-II receptor antagonist and a calcium channel blocker for the treatment of hypertension. The '904 Patent also teaches that "the combinations of active compounds can be administered alone, but are generally administered with a pharmaceutical carrier selected on the basis of the chosen route of administration and standard pharmaceutical practice." It also teaches

that "[t]he combinations of this invention can be administered for the treatment of hypertension" and that the "[p]harmaceutical compositions of the invention may contain from 10 to 300 mg of the desired calcium channel blocker and 1 to 100 mg of the angiotensin-II receptor antagonist per unit dose one or more times daily." The '904 Prior Art Patent also references certain disease states involving "diabetic" conditions.

60. Although the '904 Prior Art Patent does not explicitly reference valsartan, that is completely unsurprising. The patent application that issued as the '904 Prior Art Patent was filed on July 28, 1994, whereas the prior art '578 Patent disclosing valsartan did not issue until March 21, 1995. Thus, the '904 Prior Art Patent was filed before valsartan was publicly disclosed by the '578 Patent. However, as soon as the '578 Patent was issued and disclosed valsartan, it would have been obvious to use valsartan as the angiotensin-II receptor antagonist in the combination treatment taught by the '904 Prior Art Patent.

61. No valid claim of the '197 Patent was infringed by Par's ANDA No. 90-011 or the manufacture or sale of Par's generic version of Exforge. The '197 Patent issued on September 25, 2001 from an application filed on June 18, 1997. The '197 Patent includes fifty-three (53) claims, only four of which are independent claims. "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Each of the independent claims in the '197 Patent requires a compressed solid dosage form (or a process for forming or method of using such a compressed solid dosage form) comprising either (1) greater than 35% by weight valsartan; and/or (2) the active ingredient hydrochlorothiazide ("HCTZ") in combination with valsartan. Neither Exforge nor any generic version of Exforge

contains or could contain the active ingredient HCTZ. Accordingly, the claims of the '197 Patent could cover a generic version of Exforge only if valsartan were present at greater than 35% by weight of the dosage form. On information and belief, at all relevant times, Par's generic version of Exforge contained less than 35% by weight valsartan, and thus could not literally infringe any of the claims of the '197 Patent.

62. As a matter of law, the claims of the '197 Patent cannot cover generic versions of Exforge that contain 35% or less by weight valsartan under the doctrine of equivalents. First, "[a] doctrine of equivalents theory cannot be asserted if it will encompass or 'ensnare' the prior art." *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017). Here, the '578 Patent is prior art to the '197 Patent and discloses a tablet that is 35.7% by weight valsartan. '578 Patent at 63:24-52 (example 93). Any doctrine of equivalents theory that encompassed a compressed solid dosage form having 35% or less valsartan would therefore improperly cover the prior art. Second, "[i]f a theory of equivalence would vitiate a claim limitation . . . then there can be no infringement under the doctrine of equivalents as a matter of law." *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998); *see also Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) ("[T]o allow what is undisputedly a minority (i.e., 47.8%) to be equivalent to a majority would vitiate the requirement that the 'first and second longitudinal strips of adhesive . . . extend the majority of the lengths of said longitudinal marginal portions.'"). Here, allowing a claim limitation that requires solid dosage forms comprising "more than" 35% by weight valsartan to cover solid dosage forms having "less than" 35% by weight valsartan would vitiate a claim limitation and would therefore be improper.

63. In addition, the relevant claims of the '197 Patent are invalid. The earliest effective filing date for the '197 Patent is June 18, 1997, and therefore, the '578 Patent that issued on March 21, 1995 is prior art to the '197 Patent. Claim 1 of the '197 Patent, for example, recites the following:

> 1. A compressed solid dosage form comprising a) an active agent containing an effective amount of Valsartan or a pharmaceutically acceptable salt thereof; and, b) at least one pharmaceutically acceptable additive wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid dosage form.

The '578 Patent anticipates this claim, rendering it invalid. More specifically, the prior art '578 Patent teaches a tablet (i.e., a compressed solid dosage form) comprising 35.7% valsartan and a number of pharmaceutically acceptable additives including, for example, lactose.

64. The Patent Office examiner did not understand that example 93 of the '578 Patent related to valsartan. Valsartan is a generic name for the chemical compound (S)-N-(1- carboxy-2-methylprop-1-yl)-N-pentanoyl-N-[2'-(1H-tetrazol-5-yl)-biphenyl-4-ylmethyl-] amine. The '578 Patent does not use the term "valsartan" but rather referred to the compound by its chemical name. Had the examiner understood that that example 93 of the '578 Patent referred to valsartan, he would have rejected claim 1 under 35 U.S.C. § 102.

65. Rather than disclose to the examiner that example 93 of the '578 Patent related to valsartan, the applicants exploited the examiner's lack of appreciation. For example, when the examiner rejected the claims based on a different prior art reference, the applicants made arguments that could not have been made had the examiner appreciated example 93 of the '578

Patent. For example, after the examiner rejected the pending claims based in part on the Muller prior art reference, the applicants argued:

> In this case, the combination of references cited by the Examiner provides no teaching, suggestion or motivation to produce the solid dosage forms of valsartan as claimed by Applicant. Muller teaches a valsartan capsule and does not teach whether the capsule is a compressed dosage form. Muller also fails to disclose any detail about the formulation of the valsartan capsule. Indeed, Muller lacks any disclosure regarding the relative weight of valsartan in the capsule.

Notably, the teaching that the applicants argued was absent from the prior art references cited by the examiner was precisely the teaching supplied by the prior art '578 Patent. The applicants also argued that "[t]he unique chemical properties of angiotensin type II receptor antagonists have made it difficult in some cases to develop formulations useful for the creation of tablets." But again, this argument could not have been made had the examiner known that the prior art '578 Patent taught a tablet form of valsartan.

66. As another example, claim 5 of the '197 Patent depends from claim 1 and recites that the valsartan dosage range is from "40 to 160 mg." Example 93 of the '578 Patent taught a 100 mg valsartan dosage and therefore the '578 Patent also anticipates and renders invalid claim 5.

67. The fact that Novartis never sued Par on the '197 or '728 Patents reflects Novartis's understanding that those patents did not afford Novartis any right to exclude Par from marketing its generic version of Exforge. Nor did Novartis sue any of the other later-filing generics (discussed below), which launched after Par's 180-day exclusivity period expired, despite the fact that the '197 and '728 Patents had not yet expired.

C. Par and Synthon File ANDAs for Generic Versions of Exforge and Novartis Chooses Not to Bring Suit

68. Par and Synthon recognized the huge market potential for Exforge and, in or about the fall of 2007, were the first generic firms to file ANDAs with the FDA containing Paragraph IV certifications to certain Exforge patents.

69. Par filed ANDA 90-011 on October 1, 2007 for the 10/160, 5/160, 10/320 milligram strengths of Exforge, and was the first applicant to file a substantially complete application containing a Paragraph IV certification for those three strengths, making Par eligible for 180 days of regulatory exclusivity.

70. Synthon filed ANDA 90-144 on November 26, 2007 for the 5/320 milligram strength of Exforge and was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 5/320 mg strength, making Synthon eligible for 180 days of regulatory exclusivity for that strength.

71. Par and Synthon submitted paragraph III certifications to the ‘578 Patent (meaning that they would not seek to market a generic product prior to the expiration of the regulatory exclusivities associated with that patent on September 21, 2012) and paragraph IV certifications to the ‘197 and ‘728 Patents (meaning they sought to enter into the market prior to the expiration of those patents on the grounds that the patents were invalid, unenforceable, and/or would not be infringed by Par’s or Synthon’s generic products). Therefore, on or shortly after October 1, 2007, and November 26, 2007, respectively, Par and Synthon disclosed their intention to market their AB-rated generic products as early as September 21, 2012.

72. Because Par and Synthon were the first companies to file substantially complete ANDAs with paragraph IV certifications, they stood to receive a significant and valuable benefit under the Hatch-Waxman Act (21 U.S.C. 355(j)(5)(B)(iv)): 180-days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Exforge.

73. After receiving confirmation from the FDA that their ANDAs had been received, Par and Synthon sent notice to Novartis of their paragraph IV certifications in letters that included a detailed factual and legal statement as to why the '197 and '728 Patents were "invalid, unenforceable, and/or not infringed" by Par's and Synthon's proposed ANDA products (the "paragraph IV Notices"). The paragraph IV Notices included an offer of confidential access to Par's and Synthon's ANDAs as required under Hatch-Waxman. The paragraph IV Notices allowed Novartis to bring a pre-marketing patent infringement action under the Hatch-Waxman Act.

74. Novartis did not file a lawsuit against Par or Synthon for infringement of the '197 and '728 Patents within the 45-day time period set forth in the statute to trigger a 30-month stay of ANDA approval. Accordingly, no 30-month stay ever went into effect for the Par or Synthon ANDAs.

75. On March 19, 2010, the FDA granted tentative approval to Par's ANDA for the generic version of Exforge, determining that, aside from existing patent or regulatory exclusivities, Par's generic Exforge was otherwise approvable and satisfied all bioequivalence, CMC, and labeling requirements.

76. Therefore, as of March 19, 2010, the only thing preventing Par from obtaining final FDA approval and launching its generic Exforge was the last two-and-a-half years of protection afforded by the '578 Patent covering the active ingredient valsartan.

77. Par intended to launch as soon as the '578 Patent expired. In 2008, Paul Campanelli, the President of Par's Generics Division, publicly stated during Par's First Quarter 2008 earnings call that Par expected to launch a generic of Exforge in 2012 (i.e., when the '578 Patent expired but well before the expiry of the '197 or '728 Patents). A contemporaneous Par press release said the same thing.

78. Instead of suing (which it knew would have been futile), Novartis reached an agreement with Par to abandon its efforts to launch generic Exforge as early as possible after the expiration of the '578 Patent and instead delay its launch until September 30, 2014, roughly two years after expiry of the '578 Patent. In exchange, Novartis agreed not to launch an authorized generic of Exforge for the first six months after Par's entry. Par could not possibly have obtained an injunction against the launch of a Novartis authorized generic version of Exforge in any patent litigation Novartis might have brought against Par.

79. Novartis provided Par with a release of its extremely weak patent claims, and a reverse payment in the form of a no-authorized-generic agreement. Novartis was motivated to do so because it was preferable to risking an adverse ruling on its patents that would have resulted in earlier generic entry. Evidence of the weakness of the '197 and '728 Patents includes:

i. Par's and Synthon's ability to develop and file ANDAs with Paragraph IV certifications within a few months of FDA approval of Exforge;

ii. Novartis's decision not to sue for patent infringement and enforce its intellectual property in court; and
iii. The facts set forth above and in Par's and Synthon's Paragraph IV certification notice letters.

80. Had Novartis filed a patent case against Par and/or Synthon based on the '197 or '728 Patents, the generic defendant or defendants would have prevailed.

81. But for the unlawful agreement between Novartis and Par, Par would have been ready, able, and willing to launch generic Exforge as early as September 21, 2012, when the '578 Patent expired, and would have requested final approval for its ANDAs well in advance of September 21, 2012. Par would have received final approval from FDA upon the expiry of the exclusivities associated with the '578 Patent on September 21, 2012. Alternatively, Par would have launched on or about March 28, 2013, when it actually received final FDA approval.

82. By 2009, Exforge was already generating hundreds of millions of dollars per year in revenues for Novartis. The loss of a substantial portion of that revenue stream upon expiry of the '578 Patent would have drastically affected Novartis's profits. Thus, Novartis had enormous incentives to avoid generic competition from Par by entering into the Agreement.

83. The unlawful agreement between Novartis and Par included confidentiality provisions precluding the parties from disclosing key terms of the agreement, including Novartis's covenant not to launch a competing authorized generic of Exforge during Par's six-month exclusivity period. Although Novartis and Par subsequently made vague public references to their agreement, they concealed its anticompetitive purpose and terms. For example, a January 2012 analyst presentation by Par lists a "Synthon/Exforge" "Business Development" arrangement in 2011. And, Par's 10-K for the fiscal year ending December 31,

2011 states that "[o]n November 30, 2011, we entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc., and on December 30, 2011, we closed on our acquisition, of Synthon's ANDA for amlodipine besylate and valsartan (5 mg/320 mg and 10 mg/320 mg) fixed dose combination tablets, a generic version of Exforge®, for $9,600 thousand. Under the terms of a separate license agreement with Novartis Pharmaceuticals Corporation, we have a certain launch date in October 2014." Similarly, Novartis's 20-F for the fiscal year ending December 31, 2011, filed on January 25, 2012, states: "In the US, under a license agreement with a generics manufacturer, the product [Exforge] is expected to face generic competition beginning in October 2014."

84. Nowhere in these disclosures did Defendants disclose the anticompetitive no-authorized-generic provision—i.e., they did not disclose that they arrived at an October 2014 generic launch date only as a result of a *payment* from Novartis to Par to delay its entry to that date. Plaintiffs lacked sufficient indication of any *quid pro quo* until Novartis actually launched its authorized generic on March 30, 2015, immediately upon expiration of Par's 180-day exclusivity period. Until March 30, 2015, Plaintiffs did not know and could not have learned through the exercise of reasonable diligence that the entry date was delayed by a payment. This was deliberate concealment, tolling the applicable statute of limitations.

85. Novartis's decision not to launch an authorized generic until Par's 180-day exclusivity expired does not make economic sense in the absence of the unlawful agreement. Absent that agreement, it would have been in Novartis's independent self-interest to launch its authorized generic immediately on Par's launch and thereby capture some portion (likely half) of

the generic sales. Novartis only agreed to delay its authorized generic launch as *quid pro quo* for Par's agreement to delay generic Exforge competition.

86. As consideration for Par's agreement to forgo selling generic Exforge in competition with Novartis's branded Exforge until almost two years after the expiration of the '578 Patent, Novartis agreed to share with Par the monopoly profits from sales of branded Exforge in the form of a covenant not to compete with Par's generic using an authorized generic. Instead of competing, which would have resulted in lower prices and lower profits for both companies, Novartis and Par unlawfully agreed to keep prices of the drug at supracompetitive levels.

87. The agreement benefitted Par by ensuring that it would be the sole generic on the market during its 180-day exclusivity period, which more than doubled Par's anticipated sales revenues in the exclusivity period because: (1) Par would capture all of the sales that would otherwise have gone to the authorized generic, and (2) Par would be able to charge significantly higher prices for its generic product as the only seller of generic Exforge on the market.

88. A brand company's launch of its own competing authorized generic is costly to any first-filer generic, such as Par, because the authorized generic takes a significant share of generic sales and pushes down generic prices substantially. The authorized generic also cuts into the first-filer's long term "first mover advantage." If the first filer is the only generic available for 180 days, Plaintiffs and other purchasers will purchase the generic from the first filer and are less likely to switch to an authorized generic when the authorized generic becomes available.

89. Thus, Novartis's agreement not to launch an AG during Par's exclusivity period was extremely valuable to Par. As Novartis has stated in its regulatory filings, "authorized

generics also reduce the value of the exclusivity for the company that invested in creating the first generic medicine to compete with the originator product."

90. Novartis's agreement not to launch an authorized generic was more valuable to Par than it was costly to Novartis. Absent the unlawful Agreement, it would have made economic sense for Novartis to launch an authorized generic immediately upon launch by an ANDA filer so that Novartis could capture half of the generic sales that would otherwise go to Par. However, those sales would have been made at lower prices because of the competition between Par's generic and the Novartis authorized generic. By agreeing not to launch an AG, Novartis gave up the sales that would have been made at those lower prices, while Par received both those sales *and* the higher prices that the absence of an authorized generic made possible.

91. The no-AG provision represented a very large payment from Novartis to Par. Specifically, as early as May 2006, financial analysts and the media were projecting annual peak sales for Exforge of $500 million. Similarly, during Novartis's third quarter, 2007 earnings call, Thomas Ebeling, the CEO of its pharma division, expressed optimism that Exforge would become a "blockbuster drug" in the United States, which is an industry designation for drugs that reach $1 billion in sales. By 2014, Novartis's annual Exforge sales were over $414 million. Using the most conservative of these numbers, Defendants could assume that 6 months of brand sales (the duration of Novartis's covenant not to launch an authorized generic) would generate revenue of at least $207 million (half of $414 million).

92. AB-rated generics take at least 80% of the brand product's unit sales over the first six months, regardless of how many generic versions of the drug are on the market. Thus, approximately $165.6 million worth of brand sales would be converted to the generic ($207

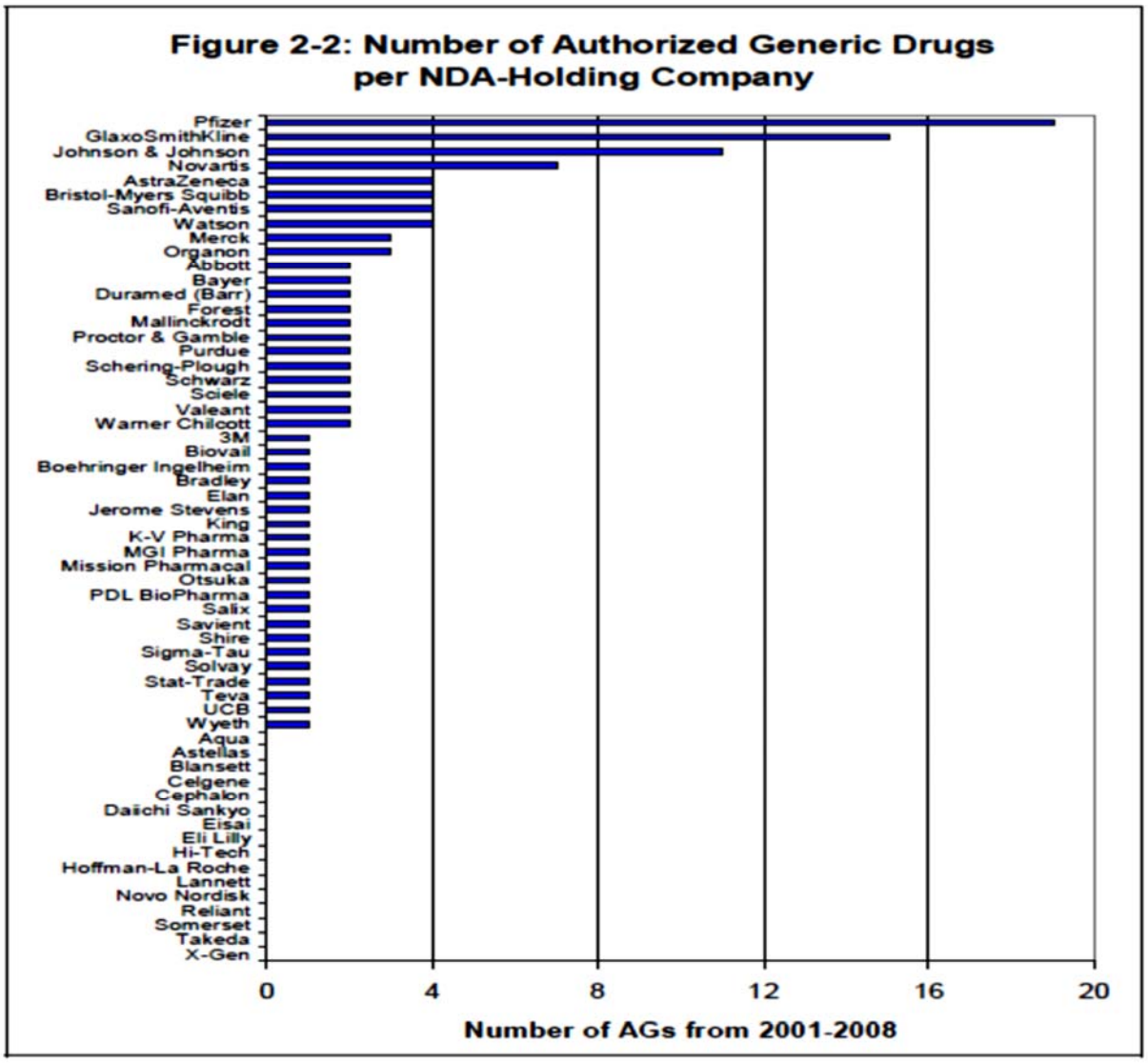
million x 0.8) during Par's 180-day exclusivity. With only one generic on the market, the generic is typically priced at approximately 70% of the brand, which would result in generic sales of approximately $115.92 million ($165.6 million x 0.7). Since Par was entitled to 180 days of exclusivity, it did not have to fear competition from any generics other than a potential AG. Thus, without competition from a Novartis AG, Par could expect to garner all of the generic sales for six months at the high, one-generic price, or approximately $115.92 million in sales.

93. Par's profit expectations would have been dramatically different if it faced competition from an AG. The addition of an AG drives the average generic price down to 50% of the brand price or less. Thus, while the generics would still take 80% of brand sales, or $165.6 million, the dollar value of those generic sales would drop to $82.8 million ($165.6 million x 0.5) or less. And, it would reasonably be expected that those sales would be split equally between Par and Novartis's authorized generic. Thus, facing competition from an AG, Par's expected sales of generic Exforge during the first 6 months would be no more than $41.4 million ($82.8 million x 0.5). By the same reasoning, Novartis would be expected to garner the other half of the $82.8 million in generic sales, or $41.4 million.

94. As a result, the expected value to Par of the no-AG clause was approximately $74.52 million in sales ($115.92 million - $41.4 million), while the expected cost to Novartis was approximately $41.4 million in sales. In both cases, a high percentage of these dollar sales would be retained as profit. Thus, Novartis's agreement to not launch an AG for 6 months represented a payment to Par of $70 million or more.

95. Novartis, which owns the generic pharmaceutical company Sandoz, Inc. ("Sandoz"), has a history of launching authorized generic versions of its own branded products in the face of actual or impending competition from ANDA-filing generic manufacturers. The FTC found that, in the time period from 2001 to 2008, only three companies launched more authorized generics than Novartis:[1]

[1] Authorized Generic Drugs at p. 16 ("For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.").



96. Novartis launched at least nineteen authorized generics between 2005 and 2016, including authorized generic versions of Exelon, Famvir, Focalin XR, Lescol XL, Lopressor HCT, Lotrel, Patanase, Patanol, Ritalin, Ritalin SR, Sandostatin, Tegretol XR, Tobi, Tobradex, Trileptal, Voltaren, Voltaren XR, Ciloxan and VivelleDot.

97. It is economically rational for a brand manufacturer that intends to launch an authorized generic to do so contemporaneously with the first ANDA filer's launch. Launch of an additional generic has no effect on the rate of generic substitution but allows the brand manufacturer to capture some portion (in most cases roughly half) of the generic sales that would otherwise go entirely to the ANDA filer.

98. Novartis itself stated in public SEC filings that "[t]he company that launches an authorized generic typically launches its product at the same time as the generic exclusivity holder."

99. Thus, it would have been economically rational for Novartis to have launched its authorized generic version of Exforge upon market entry by Par. Absent its agreement with Par, it would have done so.

100. Even under the most conservative estimates, the payment flowing from Novartis to Par via the no-AG agreement had a value of approximately 70 million dollars. Novartis intended the payment to induce Par to stay out of the market for Exforge and its generic equivalents in return for sharing monopoly profits among Defendants, a naked horizontal market-allocation agreement and thus a per se violation of the Sherman Act. Alternatively, the agreement includes a large and unexplained reverse payment to Par for delaying the launch of generic Exforge and is unlawful under the rule of reason.

101. Absent Novartis's unlawful reverse payment to Par, any agreement to settle Novartis's patent claims would have resulted in an earlier entry date than the date Novartis and Par agreed to with the reverse payment. But for the agreement, Par would have launched generic Exforge as early as September 21, 2012, but, in any case, no later than March 28, 2013 (when its

ANDA received final FDA approval). This is evident from the fact that numerous manufacturers of generic Exforge, including at least Mylan, N.V., ("Mylan"), Teva Pharmaceutical Industries, Ltd. ("Teva"), Torrent Pharms, Ltd. ("Torrent"), Novel Labs, Inc. ("Novel") and Lupin Pharmaceuticals, Inc. ("Lupin"), all launched on or about March 30, 2015, when Par's 180-day exclusivity expired, but before the expiration of the '197 and '728 Patents, and without a license from Novartis. Novartis also would have launched its authorized generic simultaneously with Par's launch.

102. Had Par launched its generic Exforge earlier than it actually did, at least one subsequent filer would have obtained final FDA approval and launched its generic equivalent of Exforge immediately upon expiration of Par's 180-day exclusivity period. But for Defendants' unlawful agreement, one or more other generic manufacturers, including some or all of the manufacturers identified in the prior paragraph, would have launched earlier than they actually did, lowering generic prices farther still.

103. According to information available publicly through the FDA, in addition to Par and Synthon, at least eight additional companies filed ANDAs to sell generic Exforge:

Application No.	Company
202713	Alembic Pharms. Ltd.
206512	Aurobindo Pharma. Ltd.
205137	Invagen Pharms.
090245	Lupin
090483	Mylan Pharms. Inc.
202829	Novel Labs. Inc.
091235	Teva Pharms. USA
202377	Torrent Pharms. Ltd

104. According to information available publicly through the FDA, many of these entities received final approval on or around the end of Par's actual 180-day exclusivity of March 30, 2015. These approvals would have been granted earlier if Par's 180-day exclusivity had been triggered earlier, as it would have been absent the unlawful agreement.

105. But for the agreement and Defendants' ongoing compliance with it, generic and authorized generic competition for Exforge would have occurred earlier and prices for fixed combination products comprising valsartan and amlodipine would have decreased. Generic and authorized generic versions of Exforge would have become available as early as September 21, 2012. Plaintiffs and their assignors would have paid lower prices for Exforge and its generic equivalents. Defendants, by their conduct, have injured Plaintiffs by causing them to pay millions of dollars in overcharges on their purchases of fixed combination products comprising valsartan and amlodipine.

VI. CLAIM ACCRUAL AND TOLLING

106. The limitations period applicable to Plaintiffs' claims has been tolled since the filing of the first direct purchaser class action complaint asserting similar claims, *Drogueria Betances, LLC v. Novartis Pharm. Corp.*, Case No. 1:18-cv-04361-AKH, on May 16, 2018. Thus, without the benefit of any tolling other than class action tolling, Plaintiffs can recover overcharge damages at least on all purchases of Exforge or its generic equivalents that occurred on or after May 16, 2014.

107. Plaintiffs' pre-May 16, 2014 damages claims are also timely under the doctrine of fraudulent concealment.

108. That doctrine applies because (1) Defendants concealed the existence of Plaintiffs' cause of action; (2) Plaintiffs remained in ignorance of the cause of action until approximately March 31, 2015, and filed within four years of that date; and (3) Plaintiffs exercised reasonable diligence to protect their rights and/or could not have discovered the existence of the cause of action through the exercise of reasonable diligence.

109. Specifically, Defendants concealed from Plaintiffs the most significant terms of the unlawful agreement between them, pursuant to which Novartis agreed to delay launching an authorized generic during Par's 180-day exclusivity period. Even when limited information about the agreement was made available in SEC filings, that key illegal aspect was not disclosed.

110. Moreover, the agreement was inherently self-concealing. Without secrecy, the agreement would not have succeeded, because of, inter alia, the availability of injunctive relief to prevent it.

111. Plaintiffs remained in ignorance of this cause of action until a date less than four years prior to the commencement of this action, and their continuing ignorance was not attributable to any lack of reasonable diligence on their part.

112. Specifically, Plaintiffs had no knowledge of Defendants' illegal and anticompetitive conduct until approximately March 30, 2015, when Novartis launched an authorized generic immediately upon the expiration of Par's 180-day exclusivity. Novartis's launch showed that it was in Novartis's economic interest to launch an authorized generic, and its only possible reason for waiting until the conclusion of Par's 180 days of exclusivity was that it had agreed to do so.

113. Because Defendants concealed their illegal no-AG agreement, there was no way for Plaintiffs to know about it until Novartis actually launched an AG when it was first permitted to do so under the agreement.

114. Plaintiffs monitor industry information sources on generic launch timing as part of their business planning and inventory management practices. Here, Plaintiffs had no knowledge of Defendants' unlawful conduct and could not have uncovered the existence of Defendants' unlawful conduct through the exercise of reasonable diligence prior to March 30, 2015.

VII. ANTICOMPETITIVE EFFECT

115. The unlawful agreement between Novartis and Par enabled Defendants to: (a) prevent and delay the entry of less expensive generic versions of Exforge products in the United States; (b) fix, raise, maintain, or stabilize the price of Exforge products; (c) allocate 100% of the U.S. market for Exforge and its generic equivalents to Novartis until September 30, 2014; and (d) allocate 100% of U.S. generic sales for Exforge to Par until March 30, 2015.

116. The '578 Patent expired on March 21, 2012, and the accompanying pediatric exclusivity expired on September 21, 2012. Par launched its generic version of Exforge on September 30, 2014, and at least five later-filing generics (Mylan, Teva, Torrent, Novel and Lupin) launched their generic versions on or shortly after March 30, 2015. Novartis launched an authorized generic of Exforge on or shortly after March 30, 2015 through its subsidiary, Sandoz.

117. But for the continuing illegal agreement between Par and Novartis, Par would have begun selling a less expensive AB-rated generic version of Exforge as early as September

21, 2012, but no later than March 28, 2013. Such sales would have occurred via market entry by Par upon Par's final FDA approval after expiry of the regulatory exclusivities associated with the '578 Patent on September 21, 2012, or shortly thereafter under a license with Novartis that did not include a no-AG provision. In addition, upon market entry by Par, and simultaneously therewith, Novartis would have begun selling its own less expensive authorized generic version of Exforge in direct competition with the Par generic. Other generic versions of Exforge, including but not limited to the Mylan, Teva, Torrent, Novel and Lupin products, would have been launched 180 days after the launch by Par.

118. An increasingly competitive market for Exforge and its generic equivalents would have thereafter emerged as additional generic manufacturers entered the market.

119. Defendants' unlawful concerted action delayed and suppressed the sale of generic Exforge in the United States, and unlawfully enabled Novartis to sell Exforge, and Par to sell its generic equivalent of Exforge, at artificially inflated, supracompetitive prices.

120. Thus, Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

121. During the relevant period, Plaintiffs and/or their assignors purchased substantial amounts of Exforge directly from Novartis and substantial amounts of generic Exforge from Par or other manufacturers. As a result of Defendants' unlawful conduct, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their requirements of fixed combination products comprising valsartan and amlodipine. Those prices were substantially greater than the

prices that Plaintiffs and/or their assignors would have paid for those products absent the illegal conduct alleged herein. But for that conduct, Plaintiffs and/or their assignors would have substituted lower-priced generic Exforge for higher-priced branded Exforge and would have paid lower prices for generic Exforge when it ultimately became available in 2014.

122. As a consequence of Defendants' unlawful conduct, Plaintiffs have sustained substantial injury to their business and property in the form of overcharges on both branded and generic Exforge. The amount and elements of such damages will be calculated after discovery and upon proof at trial.

123. Defendants are serial antitrust violators. Novartis's subsidiary Sandoz, then known as Geneva Pharmaceuticals, Inc., was a defendant in an early reverse-payment case involving the drug Hytrin. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *overruled*, 570 U.S. 136 (2013). Defendant Par Pharmaceutical, Inc. is a defendant in reverse-payment litigation involving the drug AndroGel. *See In re AndroGel Antitrust Litig.*, 2018 WL 2984873 (N.D. Ga. June 14, 2018). The Court has authority to enjoin Defendants from committing further antitrust violations.

IX. INTERSTATE COMMERCE

124. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful conduct, as alleged above, has occurred in, and has had a substantial impact on, interstate commerce.

X. MONOPOLY POWER AND MARKET DEFINITION

125. At all relevant times, Novartis had and maintained monopoly power in the market for Exforge and its generic equivalents because it had the power to maintain the price of fixed combination products comprising valsartan and amlodipine at supracompetitive levels without losing sales.

126. Direct proof exists that Novartis had monopoly power over the price of fixed combination products comprising amlodipine and valsartan. Such direct evidence includes, among other things, the abnormally high price-cost margins enjoyed by Novartis prior to entry of generic Exforge and Novartis's ability to profitably maintain the price of Exforge well above competitive levels.

127. Manufacturers attempt to differentiate brand name drugs like Exforge based on features and benefits (including safety and efficacy), and not on price. Physicians and patients are generally price-insensitive when prescribing and taking prescription drugs like Exforge. As described above, physicians are not generally aware of the relative price of various therapeutic alternatives and do not make prescribing decisions on the basis of relative prices. In addition, the presence of health insurance that includes pharmacy benefits insulates most patients from the cost of prescription drugs and other institutional features of the pharmaceutical marketplace. The result is that other drugs within its same therapeutic class do not constrain the price of Exforge.

128. Other drugs that are not AB-rated to Exforge cannot be substituted automatically for Exforge by pharmacists, do not exhibit substantial cross-price elasticity of demand with

respect to Exforge, and thus are not economic substitutes for, nor reasonably interchangeable with, Exforge.

129. Other drugs used to treat the same condition as Exforge are not economic substitutes for Exforge or its generic equivalents, and the existence of those other products have not constrained Novartis's pricing of Exforge to a competitive level. Novartis has never lowered the price of Exforge in response to the pricing of other branded or generic treatments.

130. Novartis needed to control only Exforge and its AB-rated generic equivalents, and no other products, in order to maintain the price of Exforge profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Exforge would render Novartis unable to profitably maintain its prices of Exforge without losing substantial sales.

131. To the extent Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, the only relevant market is Exforge (in all its forms and dosage strengths), and AB-rated generic versions of Exforge. The relevant geographic market is the United States.

132. Novartis's anticompetitive payment to Par demonstrates that Novartis enjoyed monopoly power with respect to Exforge (in all its forms and dosage strengths) and bioequivalent generic versions of Exforge.

133. A small but significant non-transitory price increase above the competitive level for Exforge by Novartis would not cause a loss of sales sufficient to make the price increase unprofitable.

134. At competitive price levels, Exforge does not exhibit significant positive cross-price elasticity of demand with any product other than AB-rated generic versions of Exforge.

135. Novartis, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections, and high costs of entry and expansion.

136. Defendants' anticompetitive conduct significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination or reduction of lower cost generic Exforge throughout the United States.

137. Novartis has maintained and exercised the power to exclude and restrict competition to Exforge and AB-rated generics.

138. At all relevant times, Novartis's market share in the relevant market was 100%, implying substantial monopoly power.

XI. CLAIMS FOR RELIEF

COUNT ONE:
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(CONSPIRACY IN RESTRAINT OF TRADE)

139. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 138 above. This claim is asserted against all Defendants.

140. Novartis and Par entered into a continuing unlawful conspiracy in restraint of trade and commerce in Exforge and its generic equivalents, the purpose and effect of which were to: (a) allocate all sales of fixed combination products comprising amlodipine and valsartan in the United States to Novartis until September 2014; (b) fix the price which Plaintiffs and/or their assignors would pay for Exforge and its generic equivalents at a supracompetitive price; and

(c) allocate all sales of generic fixed combination products comprising amlodipine and valsartan in the United States to Par from September 2014 until March 2015.

141. The unlawful agreement between Novartis and Par was a temporal horizontal market-allocation agreement, a horizontal output restriction and a horizontal price-fixing agreement, and thus a per se violation of section 1 of the Sherman Act. Par agreed not to compete with Novartis from the date of the agreement until September 30, 2014, and Novartis agreed not to compete with Par from September 30, 2014 until March 30, 2015. Likewise, both companies reciprocally agreed to restrict their output of generic Exforge to zero—Par agreed to do so from the date of the agreement until September 30, 2014, and Novartis agreed to do so from September 30, 2014 to March 30, 2015. Finally, Novartis retained the right to sell branded (high-priced) Exforge from September 30, 2014 to March 30, 2015, but agreed not to sell generic (low-priced) Exforge in competition with Par during that period—a horizontal price-fixing agreement. Horizontal market-allocation agreements, output restrictions, and price-fixing agreements are illegal per se.

142. In the alternative, Novartis and Par entered into an agreement that included a large and unexplained payment from Novartis to Par in exchange for Par's agreement to delay the launch of generic Exforge. That agreement had substantial anticompetitive effects in the relevant market by creating and maintaining monopoly power and is unlawful under the rule of reason. There is no legitimate, procompetitive justification for Defendants' agreement that outweighs its harmful effect. Even if there were some conceivable justification, Defendants' agreement is broader than necessary to achieve such a purpose.

143. Plaintiffs have been injured in their business and property by reason of Novartis and Par's unlawful contract, combination, and conspiracy. Plaintiffs have paid more to purchase both branded and generic Exforge during the relevant period than they would have paid in the absence of Defendants' unlawful conduct.

144. Defendants' conduct threatens continuing damage and injury to Plaintiffs unless enjoined by this Court.

COUNT TWO:
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(MONOPOLIZATION – NOVARTIS)

145. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 138 above. This claim is asserted against Novartis.

146. At all relevant times, Novartis possessed monopoly power in the relevant market.

147. Novartis used willful and exclusionary means as part of a scheme to improperly maintain and extend its monopoly power in the relevant market, as detailed above.

148. The goal, purpose, and/or effect of the scheme was to prevent and delay the entry of generic competitors that would have sold generic versions of Exforge in the United States at prices significantly below Novartis's prices for branded Exforge, which would have effectively caused the average market price of fixed combination products comprising amlodipine and valsartan to decline dramatically. By delaying the entry of such competitors, Novartis maintained its ability to charge supracompetitive prices without losing significant sales.

149. The goal, purpose and effect of Novartis's scheme was to maintain and extend Novartis's monopoly power with respect to Exforge and its generic equivalents.

150. But for Novartis's ongoing, illegal anticompetitive conduct, generic versions of Exforge would have become available as early as September 21, 2012, and additional generic entrants would have launched sooner than they actually did.

151. Plaintiffs have been injured in their business and property by reason of Novartis's unlawful monopolization. Plaintiffs have paid more to purchase both branded and generic Exforge during the relevant period than they would have paid in the absence of Novartis's unlawful conduct.

152. Novartis's conduct threatens continuing damage and injury to Plaintiffs unless enjoined by this Court.

COUNT THREE:
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(ATTEMPT TO MONOPOLIZE - NOVARTIS)

153. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 138 above. This claim is asserted against Novartis.

154. Novartis, through its anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Novartis's conscious objective to control prices and/or to exclude competition in the relevant market.

155. The natural and probable consequence of Novartis's anticompetitive scheme, which was intended by, and plainly foreseeable to, Novartis, was to control prices and exclude competition in the relevant market.

156. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Novartis would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

157. Plaintiffs have been injured in their business and property by reason of Novartis's unlawful attempt to monopolize. Plaintiffs have paid more to purchase both branded and generic Exforge during the relevant period than they would have paid in the absence of Defendants' unlawful conduct.

158. Defendants' conduct threatens continuing damage and injury to Plaintiffs unless enjoined by this Court.

COUNT FOUR:
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE)

159. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 138 above. This claim is asserted against all Defendants.

160. Defendants Novartis and Par combined, conspired and contracted between and among themselves to unlawfully monopolize trade in Exforge and its generic equivalents in the United States.

161. Novartis and Par each committed at least one overt act in furtherance of the conspiracy.

162. Novartis and Par had a specific intent to achieve or maintain monopoly power.

163. The purpose and effect of the conspiracy was to create and maintain market power and to fix, raise, stabilize and maintain the prices for Exforge and its generic equivalents at supracompetitive levels.

164. Plaintiffs have been injured in their business and property by reason of Novartis and Par's unlawful conspiracy. Plaintiffs have paid more to purchase both branded and generic Exforge during the relevant period than they would have paid in the absence of Defendants' unlawful conduct.

165. Defendants' conduct threatens continuing damage and injury to Plaintiffs unless enjoined by this Court.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. Permanent injunctive relief (i) enjoining Defendants from continuing their illegal conduct; (ii) enjoining Defendants from engaging in future anticompetitive conduct with the purpose or effect of delaying the entry of other generic drugs; and (iii) requiring Defendants to take affirmative steps to dissipate the continuing effects of their prior unlawful conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XIII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: March 22, 2019

Respectfully submitted,

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